UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
Fort Worth Division

Outsourcing Facilities Association, *et al.*, Plaintiffs, v. U.S. Food and Drug Administration, *et al.*, Defendants, and Novo Nordisk Inc., Intervenor-Defendant.	Case No. 4:25-cv-174-P

Federal Defendants' Opposition to Plaintiffs' Motion for a Preliminary Injunction

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INTRODUCTION

Congress authorized the Food and Drug Administration (FDA) to determine whether a drug is "in shortage in the United States." FDA's determination of a drug shortage triggers a variety of statutory mechanisms designed to alleviate the shortage and provide additional flexibilities to mitigate the disruption the shortage may cause. One such mechanism involves compounded drugs—medications that FDA does not approve or evaluate for safety, effectiveness, or quality before they are marketed. Ordinarily, the Federal Food, Drug, and Cosmetic Act (FDCA) restricts the compounding of drugs that are essentially copies of FDA-approved drugs. When FDA determines there is a nationwide shortage of a particular drug, however, the FDCA allows certain compounding that it would otherwise restrict. Correspondingly, once FDA finds the shortage no longer exists, the FDCA's temporary allowance of such compounding ends.

In 2022, FDA deemed semaglutide injection products—approved drugs manufactured and marketed by Novo Nordisk Inc. (Novo) under the names Wegovy (for type 2 diabetes) and Ozempic (for obesity)—to be in shortage. Thus, FDCA restrictions on certain compounding of semaglutide did not apply.[1] But in February 2025, after considering evidence from multiple sources—including data provided by Novo and information submitted by Plaintiffs, individual patients, and pharmacies—FDA determined that the semaglutide shortage was resolved. To avoid disruptions in patient treatment and promote an orderly transition, FDA also announced that it would temporarily not take enforcement action against compounders for certain violations of the FDCA.

Plaintiffs, a trade association for drug compounders and a pharmacy engaged in compounding, seek to preliminarily enjoin FDA's shortage determination. Plaintiffs have not clearly shown the right to extraordinary relief. First, Plaintiffs are not substantially likely to succeed on their claim that FDA's determination was arbitrary and capricious. FDA correctly

[1] For simplicity, the term "semaglutide" in this brief refers to the injection products declared to be in shortage in March and August 2022, but not other semaglutide products that have not been declared to be in shortage.

found that Novo could accommodate increases in demand, after all open orders were fulfilled, using its surplus of [redacted] of packages. FDA also reasonably credited detailed information from Novo showing that the company had fulfilled all requests for Wegovy and Ozempic—without adjustment or limitation—for [redacted]. Further, FDA considered data from compounders, such as production volume, but found this information did not undermine the agency's conclusions.

Second, Plaintiffs are not substantially likely to succeed on their claim that FDA was required to engage in notice-and-comment rulemaking. An agency generally has discretion whether to proceed by rulemaking or adjudication. Both the statutory and factual contexts here left FDA with only one viable option: adjudication. The FDCA requires that the shortage list be kept "up-to-date," prohibits disclosure of the vast majority of information FDA considers, and authorizes FDA to keep confidential even the existence of its decision. Given that, and the discrete factual issues at play, FDA permissibly made a drug shortage determination through a declaratory order. Indeed, this Court recently blessed the same procedure. *See Outsourcing Facilities Ass'n v. FDA*, No. 4:24-cv-953, 2025 WL 746028, ECF No. 100 (PI Order), 15 (N.D. Tex. Mar. 5, 2025). And even if FDA had to provide notice and an opportunity to comment, any procedural error was harmless because Plaintiffs and the public had ample opportunity to submit information.

Finally, the balance of equities and public interest weigh heavily against a preliminary injunction. The public's interest lies squarely in benefitting from the greater safety protections that apply to FDA-approved drugs rather than unapproved compounded versions. Further, the requested injunction would upset the careful balance Congress struck between incentivizing drug development and temporarily allowing certain compounding during a shortage.

For all these reasons, Plaintiffs' motion for a preliminary injunction should be denied. In addition, Federal Defendants note that the entire administrative record has been filed with the Court. *See* ECF No. 49. Accordingly, Federal Defendants suggest consolidating the preliminary injunction proceeding with summary judgment under Federal Rule of Civil Procedure 65(a)(2).

BACKGROUND

I. Statutory Background

A. FDA's regulation of drug manufacturing

The FDCA generally prohibits the introduction of a "new drug" into interstate commerce without FDA approval. 21 U.S.C. § 355(a). To obtain FDA approval, a manufacturer usually must submit a new drug application (NDA). *Id.* § 355(b)(1). FDA approves such applications only if it finds, based on the evidence before it, that the drug is safe and effective for its intended use under the conditions of use described in the drug's labeling. *Id.* § 355(c)(1)(A), (d). Once an NDA is approved, facilities producing the drug must comply with "current good manufacturing practice" (cGMP) requirements, which "assure that such drug meets the requirements of [the FDCA] as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports . . . to possess." *Id.* § 351(a)(2)(B); *see* 21 C.F.R. Parts 210, 211. An NDA approval can have significant effects on third parties, such as blocking certain applications of other manufacturers for drugs using the same active moiety for five years (often referred to as "exclusivity" for the first drug approved). *See* 21 U.S.C. § 355(c)(3)(E)(ii).

Drug compounding is generally "a process by which a pharmacist or doctor combines, mixes, or alters ingredients to create a medication tailored to the needs of an individual patient." *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 360–61 (2002). Unlike FDA-approved drugs, compounded drugs do not "undergo[] FDA premarket review for safety, effectiveness, and quality." App. 72.[2] Compounding pharmacies and physicians whose drugs meet the conditions of 21 U.S.C. § 353a ("503A compounders") are not required, among other things, to follow cGMP requirements. Under 21 U.S.C. § 353b, on the other hand, outsourcing facilities ("503B compounders") are subject to, among other things, cGMP requirements, registration, and product

[2] Citations to "App." are to the Appendix in Support of Plaintiffs' Motion for a Preliminary Injunction, ECF No. 39. Citations to "FDA App." are to Federal Defendants' Appendix in Support of this Opposition.

reporting requirements, but like 503A compounders, the drugs they manufacture do not undergo FDA premarket review for safety, effectiveness, and quality.

Of particular importance here, the FDCA restricts production by any compounder of compounded drugs that are "essentially a copy" of an FDA-approved drug. *Id.* §§ 353a(b)(1)(D), 353b(a)(5). This statutory restriction "works to protect the new drug approval process and, by extension, provides a market advantage to FDA-approved drugs" over compounded drugs. *Athenex Inc. v. Azar*, 397 F. Supp. 3d 56, 71 (D.D.C. 2019). But certain restrictions that typically apply to compounding copies of an approved drug are temporarily lifted when the drug appears on the drug shortage list. *See* 21 U.S.C. §§ 353a(b)(1)(D), 353b(a)(5).

B. Drug shortages

The FDCA defines a "drug shortage" as "a period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug." 21 U.S.C. § 356c(h)(2). Congress requires FDA to "maintain an up-to-date list of drugs that are determined by [FDA] to be in shortage in the United States." *Id.* § 356e; *see* 21 C.F.R. § 314.81(b)(3)(iii)(*f*) (adopting the definition of "shortage" from 21 U.S.C. § 356c(h)(2)). Because FDA must consider drug manufacturers' confidential commercial information and trade secrets to determine whether a drug is in shortage, Congress provided that "[n]othing in this section alters or amends" 18 U.S.C. § 1905 or 5 U.S.C. § 552(b)(4), which collectively protect such information from disclosure. 21 U.S.C. § 356e(c)(2). Further, Congress empowered FDA to "choose not to make information collected under this section publicly available" if doing so would "adversely affect the public health," such as where disclosing the information would "increas[e] the possibility of hoarding" the drug. *Id.* § 356e(c)(3).

When a drug appears on the shortage list, certain restrictions on compounding copies of the approved drug are temporarily lifted. As relevant here, the limitation on 503B compounders producing a drug that is "identical or nearly identical" to an approved drug does not apply. *Id.* § 353b(a)(5), (d)(2)(A); *see also id.* § 353b(a)(2)(A)(ii) (exemption from limitation on

compounding using bulk drug substances). Also, the limitation on 503A compounders producing "drug products that are essentially copies" of approved drugs "regularly or in inordinate amounts" does not apply to drugs on the shortage list because FDA considers those drugs not "commercially available." *Id.* § 353a(b)(1)(D).

II. Factual and Procedural Background

FDA approved Novo's NDA for Ozempic in December 2017 and its NDA for Wegovy in June 2021. App. 66. FDA added Wegovy to its drug shortage list on March 31, 2022, and added Ozempic to the list on August 23, 2022. *Id.*

On February 21, 2025, FDA issued a declaratory order finding that the shortage of semaglutide was resolved. After review of "detailed information and data regarding" Novo's production, sales, and inventory of the drugs, FDA determined that Novo was meeting or exceeding current demand. App. 63–64. FDA further found that Novo had "developed reserves" of "finished product" and "significant units of semi-finished product." App. 64. Comparing these reserves to Novo's projections for future demand, FDA concluded that Novo's supply "will meet or exceed projected demand." *Id*.

In addition to data from Novo, FDA also considered information from "patients, healthcare providers, and others, including compounders." App. 64. However, this information "ha[d] important limitations" and "[did] not undermine or outweigh" Novo's evidence that its supply was currently meeting or exceeding demand and was also likely to meet or exceed projected demand. *Id*. FDA thus declared the shortage of Ozempic and Wegovy resolved. App. 75. The Declaratory Order was supported by a decision memorandum laying out in detail the agency's analysis and conclusions. *See* App. 24–61. FDA also announced temporary enforcement discretion for certain FDCA violations involving compounded semaglutide. App. 64–65.

On March 20, 2025, Plaintiffs filed their motion for a preliminary injunction. ECF No. 37 (Mot.). Federal Defendants now oppose this motion.

LEGAL STANDARDS

A preliminary injunction is an extraordinary remedy that should only be granted "if the movant shows: (1) a substantial likelihood of prevailing on the merits; (2) a substantial threat of irreparable injury if the injunction is not granted; (3) the threatened injury outweighs any harm that will result to [a] non-movant if the injunction is granted; and (4) the injunction will not disserve the public interest." *Ridgely v. FEMA*, 512 F.3d 727, 734 (5th Cir. 2008). The third and fourth factors merge when the government is the party opposing the motion. *Nken v. Holder*, 556 U.S. 418, 435 (2009). A preliminary injunction "should not be granted unless the [movant] has clearly carried the burden of persuasion on all four requirements." *Dennis Melancon, Inc. v. City of New Orleans*, 703 F.3d 262, 268 (5th Cir. 2012) (quotation marks and citation omitted); *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008) (requiring a "clear showing").

ARGUMENT

I. Plaintiffs Have Not Shown a Likelihood of Success on the Merits

Plaintiffs have not met their heavy burden of demonstrating the likelihood that FDA acted arbitrarily or capriciously, or that it was error to proceed by adjudication rather than notice-and-comment rulemaking.

A. FDA reasonably determined that the semaglutide shortage was resolved

In an APA case, the court reviews whether the challenged action was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). "Judicial review under that standard is deferential," *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021), "narrow," *Motor Vehicle Mfrs. Ass'n, Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983), and based solely on the administrative record, *Camp v. Pitts*, 411 U.S. 138, 142 (1973) (per curiam). "A court simply ensures that the agency has acted within a zone of reasonableness and, in particular, has reasonably considered the relevant issues and reasonably explained the decision." *Prometheus Radio Project*, 592 U.S. at 423. In so doing, a court may not "substitute its judgment for that of the agency," *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971), but must instead uphold the agency's action if it is "rational, based on

consideration of the relevant factors and within the scope of the authority delegated to the agency by the statute," *State Farm*, 463 U.S. at 42; *see also FDA v. Wages and White Lion Invs., L.L.C.*, No. 23-1038, __ S. Ct. __, 2025 WL 978101, at *13 (U.S. Apr. 2, 2025). In short, FDA's decision did not "need[] to be perfect." PI Order 21.

Plaintiffs have not shown a likelihood that they can meet this demanding standard. In February 2025, the question before FDA was whether Novo's semaglutide products were "in shortage in the United States." 21 U.S.C. § 356e(a). A "shortage" is "a period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug." *Id.* § 356c(h)(2). As the decision memorandum explained, when determining if a drug is in shortage, "FDA evaluates the supply and demand or projected demand of the drug on a nationwide level, across the entire market, not at the local level." App. 27. After thoroughly considering a host of data from Novo and other sources, FDA reasonably found that "[Novo's] supply [was] currently meeting or exceeding demand and will meet or exceed projected demand across all strengths of Ozempic and Wegovy." Thus, FDA determined that the shortage was resolved. App. 29.

Novo's recent inventory records showed a surplus supply. Examining Novo's inventory reports, FDA found that "supply is meeting or exceeding demand for these drugs." App. 33. Novo maintained an excess inventory of [redacted] of Ozempic and Wegovy packages during the [redacted] immediately preceding FDA's decision, and [redacted]. From [redacted], Novo's reports showed an average net inventory (that is, inventory after fulfilling open orders) of [redacted] of packages for both Ozempic and Wegovy. *Id.* (Table 2). The net inventory of [redacted]. Likewise, Wegovy's net inventory [redacted]. *Id.* As of [redacted], after accounting for open orders, Novo's net inventory balances were [redacted] packages of Ozempic and [redacted] packages of Wegovy. App. 31 (Table 1).

Moreover, Novo's inventory of "semi-finished" products (products that were manufactured but not yet packaged) could be converted to finished products within [redacted]. App. 30–31. Novo consistently maintained [redacted] of packages of semi-finished Ozempic and Wegovy in inventory from [redacted]. App. 31. In [redacted], Novo had over [redacted] packages of semi-finished Ozempic and over [redacted] packages of semi-finished Wegovy on hand. *Id.* Novo's semi-finished product inventory "provide[d] assurance" to FDA that Novo "ha[d] the ability, beyond its finished product inventory, to supply additional finished Ozempic and Wegovy product relatively quickly to meet demand changes." App. 33.

FDA also noted that Novo had provided calculations of stock levels expressed as "days on hand"—that is, [redacted]. App. 32. As FDA observed, Novo "stated" that the days-on-hand reports showed an inventory of "[redacted]. *Id.* FDA relied on the days-on-hand data, together with Novo's net inventory data, to support the conclusion that "Novo Nordisk has been maintaining substantial product in inventory." App. 33.[3]

Novo fulfilled all orders [redacted]**.** Novo's data included [redacted] information on the quantity of its product that wholesalers and other customers "initially requested" alongside the quantity that Novo in fact supplied to them. App. 36–37. The data in Table 4 showed that Novo fulfilled every request "without adjustment or limitation" [redacted]

[3] Federal Defendants note that two columns of data in Table 3 mistakenly reported Novo's numbers for [redacted] days on hand rather than [redacted] days on hand. This transcription error is immaterial because FDA had before it and considered the correct information in Novo's submissions; the actual values supported FDA's conclusion that Novo "has been maintaining substantial product in inventory"; and the [redacted] data carried far less weight in the shortage determination than [redacted]. App. 33. For reference, the corrected values are as follows. For the week of [redacted], the reported days on hand of Ozempic 0.25MG/0.5MG, 1MG, and 2MG were [redacted] respectively. FDA App. 1. For the week of [redacted], the reported days on hand of Ozempic for those doses were [redacted] respectively. FDA App. 3. For the week of [redacted], the reported days on hand of Wegovy 0.25MG, 0.5MG, 1MG, 1.7MG, and 2.4MG were [redacted], respectively. FDA App 2. For the week of [redacted], the reported days on hand of Wegovy for those doses was [redacted] respectively. FDA App. 4.

[redacted] (the most current information available as of the date of FDA's decision). App. 36.

[redacted] App. 34–35, FDA App. 27. In response to FDA questions, Novo explained that [redacted] App. 34; *see* FDA App. 14–16. [redacted] App. 35, 40 (Table 6).

Nonetheless, only after [redacted] did FDA determine the shortage had ended. App. 34; *see* Fed. App. 13 (Novo stating that it had not limited wholesaler orders in [redacted] and had fulfilled all orders for all semaglutide injection doses during that time). "Importantly" for FDA's decision, [redacted]. App. 35. Further, FDA reasoned that Novo's "substantial stock of finished product and semi-finished product" suggested that Novo [redacted] *Id.*

Wholesalers had a consistent supply of Novo's products. Novo also reported information on wholesalers' inventory and their supply of products to retailers and pharmacies, which FDA found further demonstrated that the shortage had ended. App. 42. From [redacted] App. 40. Meanwhile, the wholesalers provided between [redacted]

[redacted] packages of Ozempic to retailers and pharmacies [redacted] packages of Wegovy [redacted]. App. 41.

Novo could meet projected demand. FDA also reasonably found that Novo's supply would meet or exceed projected demand. Novo's manufacturing capacity had [redacted], which left Novo "well positioned to respond to future changes in demand." App. 42. Most immediately, while in [redacted]. App. 45. [redacted] *See* App. 31.

Against that supply, Novo reported projected demand [redacted]. App. 42–43. Specifically, it projected a [redacted]. App. 44–45.

In addition, Novo provided information in the form of "cumulative" supply and demand for both drugs. App. 38–39 (Figures 1 and 2). [redacted], App. 38 n.61, and the [redacted] App. 38 n.62. Figures 1 and 2 "show[ed] the same trend that cumulative supply is outpacing demand" shown in other data provided by Novo. App. 38. Thus, FDA found that the "cumulative" information "further" supported a determination that the shortage was over. *Id.*

Potential increase in demand. Additionally, FDA "recognize[d] that significant compounding of semaglutide injection products is occurring, and that some patients currently

receiving those products can be expected to seek [Novo's] approved products at a future point when compounding is curtailed." App. 57. However, the information before the agency did not provide "a sufficient, reliable basis to project the scope of this effect." App. 53. Although 503B facilities reported producing about [redacted], FDA did not know how those products were prescribed or the number of doses per "package." App. 54–55. But even assuming all those products would convert to demand for Novo's products, the volume of [redacted] was dwarfed by Novo's most recently reported net inventory of over [redacted] App. 55; *see* App. 31 (Table 1). Turning to 503A compounding, the Alliance for Pharmacy Compounding (APC) claimed [redacted] semaglutide prescriptions per month and that the true volume was even higher. App. 55. However, it did not "provide[] information" showing that a higher volume of compounding was occurring. App. 56. As with 503B compounding, FDA concluded that the known volume of 503A compounding "remains small relative to [Novo's] production and inventory." App. 55–56.

FDA also observed that some patients receiving compounded semaglutide would not start treatment with Novo's products for a variety of reasons, including that Novo's products were significantly more expensive than the compounded products. App. 56. FDA thus reasonably predicted, based on the information available, that Novo's supply would be able to accommodate any increased demand from patients currently receiving a compounded product and that the information from other sources "does not alter [its] conclusions" regarding Novo's ability to meet current and projected demand. App. 45. *See State Farm*, 463 U.S. at 52 (recognizing agency authority to "exercise its judgment in moving from the facts and probabilities on the record to a policy conclusion"); *Int'l Ladies' Garment Workers' Union v. Donovan*, 722 F.2d 795, 821 (D.C. Cir. 1983) ("[T]his court must be particularly deferential when reviewing an agency's predictive judgments about areas that are within the agency's field of discretion and expertise.").

Limitations in third-party data. FDA also considered supply- and demand-related information from a variety of other sources, including Plaintiffs and individual patients and

pharmacies, as well as news articles and blog posts, comments from FDA's general compounding docket, and reports of high volume of demand for compounded semaglutide. App. 46–58. The agency "carefully evaluat[ed] the information" from those sources but determined that it "ha[d] important limitations" and thus "[did] not undermine or outweigh" evidence showing that the shortage had ended. App. 25–26.

For example, many submissions from individual patients had no indication of *when* the patient had trouble accessing semaglutide products. App. 46–47. Nor did these reports use any consistent definition for what it meant to have trouble accessing a drug, a nebulous concept that could encompass, for many of the reports, not just an out-of-stock prescription, but also an inability to get a prescription from a doctor or an inability to get insurance coverage for the drug. App. 47–48. FDA concluded that gaps in availability at individual pharmacies were likely caused by the "practical dynamics" of the supply chain between Novo's production and the end user, rather than a national shortage of the products. App. 47. FDA similarly reasoned that the same dynamics most likely explained the screenshots of wholesalers' websites that purported to indicate that wholesalers were restricting sales of Novo's products or that they lacked inventory. App. 50. Further, given the significant limitations of the screenshot evidence, and Novo's explanations, FDA concluded that "the screenshots do not provide reliable evidence in assessing whether supply of Ozempic or Wegovy is meeting demand." *Id.*

Plaintiffs fault FDA's decision, claiming that the agency misinterpreted Novo's data and failed to properly account for evidence from other sources. FDA did neither. *See Prometheus Radio Project*, 592 U.S. at 426 (rejecting APA challenge because the "FCC did not ignore the Free Press studies," it "simply interpreted them differently").

***Novo-Provided Data*.** Plaintiffs argue that FDA misinterpreted Novo's data in two principal ways. Both are red herrings. *First*, Plaintiffs claim the "primary demand data" before the agency was that shown in Figures 1 and 2 of the decision memorandum, which FDA should not have relied on because those figures reflected "[redacted]" that do not always represent demand, such as when there is a shortage. Mot. 7. However, FDA explicitly noted that [redacted] "[do] not

account for unfilled prescriptions due to lack of supply." App. 41. And Plaintiffs ignore the other, substantial evidence upon which FDA relied—such as that in Tables 4 and 5, which demonstrated that Novo fulfilled every product request [redacted] "without adjustment or limitation" and [redacted]. App. 34, 36–37. Plus, Novo fulfilled these orders while maintaining an inventory of [redacted] of packages. App. 31. Therefore, the evidence before FDA indicated that Novo was satisfying all the demand present in the market and that there was no shortage.

Still, Plaintiffs argue the data "reveal[] substantial deficiencies," citing two tables of their own creation. Mot. 9–10. On closer inspection, Plaintiffs' tables merely compare the "[redacted]" data in Tables 4 and 5 to the "[redacted]" number in Figures 1 and 2. *Compare* Mot. 9 nn.6–7*, with* App. 36–37 (Tables 4 and 5). Not only do Plaintiffs make an inconsequential comparison between different categories of statistics about sales, they fail completely to account for Novo's ample product *supply*, including the [redacted] reserve of finished and semi-finished packages of both drugs. App. 31. Rather than a shortage, Plaintiffs' comparison reveals something much more mundane: the "[redacted]" data in Tables 4 and 5 and the [redacted] in Figures 1 and 2 come from different sources and are reported in different ways. *See* FDA App. 23 n.6 (explaining that the data in Tables 4 and 5 were "[redacted]" but that Figures 1 and 2 were [redacted]").

Second, Plaintiffs speculate that Novo [redacted]." Mot. 8. Plaintiffs refer to [redacted]. App. 37. As noted above, however, Novo explained the [redacted]. *See* App. 35, 40 (Table 6). Moreover, as FDA noted, Novo had more than sufficient semi-finished product in

inventory [redacted] had Novo chosen to do so. App. 35; *see* App. 31 (Table 2); App. 37 (Table 7).

Further, FDA determined that the shortage had ended by February 21, 2025 only after receiving data from Novo indicating that it had fulfilled all [redacted]. App. 34. Plaintiffs' focus on a period preceding FDA's determination [redacted] only reinforces the reasonableness of FDA's ultimate decision, and the importance of FDA's ability to announce shortage determinations quickly.

Plaintiffs' other arguments regarding Novo's data are no more convincing. For instance, Plaintiffs complain that FDA should not have relied on Novo's demand projections because they [redacted]. Mot. 8–9. But FDA did not rely on Novo's projections alone. The agency also considered information from the compounding pharmacies themselves, App. 28–33, before making its own prediction about how reinstated restrictions on certain compounding would affect demand, App. 55–56. FDA compared this information to [redacted] and concluded that Novo would have ample product on hand to meet future demand. App. 56–57.

In asserting that "transitional increase in demand after compounding ceases may not be one-for-one, but it certainly is far from zero," Plaintiffs misunderstand FDA's analysis. Mot. 9. FDA accounted for that potential transitional increase in demand, conservatively assuming that the maximum, one-for-one increase would occur. App. 55–56. Plaintiffs similarly misunderstand Novo's data when alleging that Novo's inventory [redacted]. Mot. 14 (comparing Tables 2 and 5). The "inventory" number Plaintiffs cite is *net* inventory, *i.e.*, the inventory remaining *after* Novo fulfilled its open orders. *See* App. 31 (Table 2). Plaintiffs further argue that inventory reports, "without further information," cannot determine whether supply is meeting demand. Mot. 14. FDA again largely agreed; it considered further information, such as Novo's history of

fulfilling, "without adjustment or limitation," every [redacted] for its products. App. 34.[4]

Other Information. Plaintiffs also err when faulting FDA's interpretation of other evidence they believe shows a shortage. Mot. 16–18. Plaintiffs cite to a ten-page list summarizing screenshots and note that wholesalers listed "restricted" or "no stock" of Novo's products "from October 30 to November 15, 2024" and that one wholesaler displayed a message to that effect on November 11, 2024. Mot. 17–18 (citing App. 237–48, 476, 478–79). Notably, the screenshots only covered a 16-day period that ended more than three months before FDA determined that the shortage was over. Consistent with the statutory command, FDA appropriately focused on the most "up-to-date" information, not cherry-picked historical snapshots. Moreover, many of the screenshots do not reflect unavailability at all, but rather that wholesalers were limiting the order volume of individual customers, apparently managing their distribution for their own business reasons. *See* App. 248 (for Nov. 15, 2024, listing pages with five products being unavailable, limiting order volume for 10 products, and listing two products as having ">100" units available). And as explained above, *see supra* p. 12, FDA ultimately reasoned the wholesaler messages were more likely attributable to the practical dynamics of the supply chain between Novo's production and the end user rather than to a national shortage of the products. App. 50.

Finally, Plaintiffs fault FDA for characterizing the known volume of compounding as "small relative to" Novo's production and inventory. Mot. 18. In fact, FDA characterized the volume of compounding as "significant." App. 57.[5] Further, when predicting the effect of reduced

[4] Plaintiffs say Novo's days-on-hand numbers "should have been a blazing red flag" that FDA "failed to recognize" or "address." Mot. 15–16. However, FDA relied on the days-on-hand information only for the proposition that Novo "has been maintaining substantial product in inventory," App. 33, a conclusion amply supported by other sources in the record.

[5] To the extent Plaintiffs argue that FDA should have conducted its own study of compounding volume, Mot. 16–17, they are wrong. "The APA imposes no general obligation on agencies to conduct or commission their own empirical or statistical studies." *Prometheus Radio Project*, 592 U.S. at 427.

compounding on the demand for Novo's products, FDA conservatively assumed that all reported compounding was entering the market and every patient receiving compounded products would switch to Novo's products. App. 54–56. Even making those conservative assumptions, FDA reasonably assessed that Novo could absorb the volume of compounding given that Novo was currently meeting or exceeding demand, had ramped up its supply capabilities to [redacted], planned to [redacted] and had substantial product inventories [redacted]. App. 31, 42, 56.

At bottom, FDA's decision reflected a reasonable judgment based on the information available. *See Prometheus*, 592 U.S. at 427 ("the [agency] made a reasonable predictive judgment based on the evidence it had"). Plaintiffs are not substantially likely to show otherwise.

B. FDA reasonably proceeded by declaratory order rather than rulemaking

FDA's shortage determination was a classic adjudication under the APA because it applied the statutory definition of "shortage" to resolve a discrete controversy. Plaintiffs' arguments to the contrary inaccurately portray the nature of a drug shortage determination and rely on inapposite case law. And even if Plaintiffs were correct that notice-and-comment was required, any error would be harmless.

1. FDA properly issued a declaratory order

A. FDA properly issued its shortage determination through adjudication. Congress did not specify what procedure FDA must use to make shortage determinations. 21 U.S.C. § 356e. "Unless Congress has specified otherwise, agencies are generally free to develop regulatory standards 'either by general [legislative] rule or by individual order' in an adjudication." *Wages,* 2025 WL 978101, at *19 (quoting *SEC v. Chenery Corp.*, 332 U.S. 194, 202-203 (1947)); *see also McDonald v. Watt*, 653 F.2d 1035, 1042 (5th Cir. 1981). That decision is reviewable for an abuse of discretion. *NLRB v. Bell Aerospace Co.*, 416 U.S. 267, 294 (1974). An agency's

judgment that there is "reason to . . . develop[] its standards in a case-by-case manner" with attention to the specific facts of each case "is entitled to great weight." *Id*.

FDA reasonably concluded that adjudication was the only viable option here for multiple reasons. First, Congress requires the list to be "up-to-date." App. 70–71 (citing 21 U.S.C. § 356e(a)). The list must therefore "extend[] up to the present time" and "us[e] or includ[e] the latest facts." *Up-to-date*, Merriam-Webster New World College Dictionary (4th ed. 2009). For semaglutide, FDA considered supply-and-demand data submitted from fall 2024 through early 2025 to reach its shortage determination. *See* App. 29 n.16. Even expeditious notice-and-comment rulemaking would not permit such timely action. App. 71

In denying Plaintiffs' motion for a preliminary injunction in the related case, the Court recognized that notice-and-comment rulemaking would inhibit FDA's performance of its statutory obligations as the time required for such rulemaking would prevent the shortage list from being "up-to-date." PI Order 9 (citing 21 U.S.C. § 356e(a)). "Given the constant fluctuation in national supply and demand numbers for a given drug," the Court observed, "a rule based on data that is more than a month old cannot be said to be based on 'the latest information' available." *Id.* at 9–10. And if shortage resolution decisions required rulemaking, the Court explained, so must shortage listing decisions. *Id.* The "lengthy rule-making process" to add and subtract drugs from the shortage list "cannot be said to be congruent with Congress's mandate for the FDA to maintain an 'up-to-date list of drugs . . . in shortage in the United States.'" *Id.* at 10 (quoting 21 U.S.C. § 356e(a)).

Second, FDA could not engage in meaningful public notice-and-comment because the core, material facts were confidential. To "give interested persons an opportunity to participate," 5 U.S.C. § 553(c), an agency must "reveal[] for public evaluation" the "technical studies and data upon which the agency relies," and in particular, "the most critical factual material used by the agency," *Chamber of Commerce v. SEC*, 443 F.3d 890, 899–900 (D.C. Cir. 2006) (internal quotations omitted). Here, the most critical factual material was the manufacturer's confidential business information, all of which FDA is prohibited from disclosing. *See, e.g.*, 21 U.S.C.

§§ 331(j), 356e(c)(2); 21 C.F.R. § 314.81(b)(2)(vii)(*b*). The agency also could not summarize that data in a way that allowed for meaningful public comment; only the agency's *conclusions* based on the data are disclosable. *See* App. 25–61 (decision memorandum filed under seal). Consequently, FDA could not have issued a proposed rule to amend the shortage list that "reveal[ed] for public evaluation" the "most critical factual material" upon which the agency was relying. *Chamber of Commerce*, 443 F.3d at 899–900. As the Court correctly concluded in the related case, maintaining the confidentiality of Novo's information while also providing the public meaningful opportunity to comment was an "unattainable" goal. PI Order 9 n.3.

Third, Congress gave FDA the discretion to withhold information that is not confidential, including the very *existence* of a shortage. 21 U.S.C. § 356e(c)(3). The public-health exception authorizes FDA to "choose not to make information" on the shortage list public if it "determines that disclosure of such information would adversely affect the public health (such as by increasing the possibility of hoarding or other disruption of the availability of drug products to patients)." *Id*. That provision is fundamentally incompatible with public notice and comment. In at least those cases, FDA *must* proceed by adjudication.

B. Of the different types of adjudications under the APA, declaratory orders allow agencies to efficiently apply existing policy to a set of facts without the need for any particular party to risk penalty or sanction. 5 U.S.C. § 554(e); *see City of Arlington, Tex. v. FCC*, 668 F.3d 229, 243 (5th Cir. 2012); *Qwest Servs. Corp. v. FCC*, 509 F.3d 531, 536–37 (D.C. Cir. 2007). Drug shortage determinations, given their discrete nature and context, are well-suited to resolution through a declaratory order—as FDA did here. *See, e.g.*, *Am. Airlines, Inc. v. Dep't of Transp.*, 202 F.3d 788, 796–97 (5th Cir. 2000) (affirming agency's decision to issue a declaratory order through adjudication).

Although the "line between" adjudication and rulemaking "is frequently a thin one," *Gen. Am. Transp. Corp. v. Interstate Com. Comm'n*, 83 F.2d 1029, 1030 n.2 (D.C. Cir. 1989), FDA's shortage determination had none of the characteristics of a rule. The "basic distinction between" the two is that adjudications are "proceedings designed to adjudicate disputed facts in particular

cases," whereas rulemakings are "proceedings for the purpose of promulgating policy-type rules or standards." *United States v. Fla. E. Coast Ry. Co.*, 410 U.S. 224, 244–45 (1973); *see* 5 U.S.C. §§ 551(4) (defining "rule"), 551(6) ("order"), 551(7) ("adjudication"). FDA applied the statutory definition of shortage to "a particular set of disputed facts," *Fla. E. Coast Ry.*, 410 U.S. at 246—namely, to data demonstrating the current and projected nationwide supply and demand of semaglutide, 21 U.S.C. § 356c(h)(2). The agency did the same thing in 2022 to find there was a shortage. The difference in February 2025 was the evidence, demonstrating that FDA decides "each case upon individual grounds," *Fla. E. Coast Ry.*, 410 U.S. at 245 (citation omitted), and applies the law consistently on "a case-by-case" basis, *Bell Aerospace*, 416 U.S. at 291–94.

Moreover, FDA's findings about the availability of a particular drug as of the time of its decision are not "applicable across the board" nor "generalized [in] nature." *Fla. E. Coast Ry.*, 410 U.S. at 246. Nor were the agency's factual findings here "used in the formulation of a basically legislative-type judgment." *Id.* And in contrast to the purely "prospective application" of a rule, *id.*, FDA's adjudication determined "present rights and liabilities" by finding that there was not *presently* a shortage. *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 221 (1988) (Scalia, J., concurring) (quoting Attorney General's Manual on the APA 14 (1947)).

2. Plaintiffs are wrong that FDA had to proceed by rulemaking

Ignoring the limited and fact-specific nature of FDA's shortage determination, Plaintiffs claim that it "create[d] law by prohibiting all compounding of semaglutide" and that it was therefore a "rule." Mot. 19. They are wrong.

A. Plaintiffs first protest that FDA's shortage determination affects the rights of "thousands" of entities, suggesting that a broad impact transforms an adjudication into a rulemaking. *Id.* at 20. But "[j]ust as a class action can encompass the claims of a large group of plaintiffs without thereby becoming a legislative proceeding, an adjudication can affect a large group of individuals without becoming a rulemaking." *Goodman v. FCC*, 182 F.3d 987, 994 (D.C. Cir. 1999). And contrary to Plaintiffs' arguments, Mot. 20–21, courts have long recognized that "an

agency need not be presented with a specific dispute between two parties" to issue a declaratory order. *City of Arlington*, 668 F.3d at 243. FDA routinely conducts adjudications that yield orders affecting large numbers of third parties, and especially competitors, in a highly regulated area: the new drug approval process. *See* 21 U.S.C. § 355(d)–(g). Approval of a new drug triggers certain statutory restrictions on compounding drugs that are essentially copies of "approved drugs." *See id*. § 353b(a)(5), (d)(2)(A). And an approval can have numerous other effects on potential competitors, such as blocking even their submission of certain applications for any drug containing its same active moiety for five years. *See id*. § 355(c)(3)(E)(ii). Yet none of this makes drug approvals legislative rules. *See also Weinberger v. Hynson, Westcott and Dunning Inc.*, 412 U.S. 609, 624–26 (1973) (endorsing FDA use of declaratory orders to address "several persons or manufacturers" of generic drugs sharing common considerations).

Next, Plaintiffs contend that FDA's shortage determination cannot be an adjudication because it has "purely prospective" effects, pointing to the portion of FDA's order that discusses the agency's intentions with respect to enforcement discretion. Mot. 21. But it is unremarkable that an adjudication may "have general prospective application." *Conf. Grp., LLC v. FCC*, 720 F.3d 957, 966 (D.C. Cir. 2013) (quotation omitted). As already discussed above, FDA's shortage determination was not "purely" or even primarily prospective: the enforcement discretion included in the decision only exists because the decision determined "present rights and liabilities" established by operation of the FDCA. *Bowen*, 488 U.S. at 221 (Scalia, J., concurring) (citation omitted). Moreover, the discussion of enforcement discretion is not legislative in nature; it creates no new law and simply expresses that the agency "does not intend to take action" against compounders for certain types of violations before certain dates. App. 71–74. FDA could have achieved the same result by not taking legal action against compounders during the relevant time period without stating the agency's intentions in advance.

For similar reasons, Plaintiffs' comparison to *Safari Club International v. Zinke*, 878 F.3d 316 (D.C. Cir. 2017), is inapt. Mot. 21. Plaintiffs in that case challenged decisions of the U.S. Fish and Wildlife Service that had the effect of banning *future* importation of certain elephant

trophies. *Safari Club*, 878 F.3d at 333. Importantly, those decisions "applied to all potential imports of sport-hunted elephant trophies from Zimbabwe, not to any individual parties . . . and did not adjudicate any dispute between specific parties." *Id.* at 333–34. Applying the principle that "adjudications immediately bind parties," whereas rules have "only future effect," the D.C. Circuit held that the decisions were rules. *Id.* at 333 (citing *Bowen*, 488 U.S. at 216–17). Unlike in that case, FDA's shortage determination "undoubtably has immediate legal consequences for specific parties." PI Order 15. The decision applied immediately to Novo, which had requested that FDA remove its drug from the shortage list. In addition, immediate consequences for Plaintiffs occurred by operation of statute.

The shortage decision did not create new legislative standards that govern individual rights and liabilities and does not govern any future shortage decisions. FDA necessarily will continue to make each such decision on a case-by-case basis. *See, e.g.*, *Vanda Pharms., Inc. v. FDA*, 436 F. Supp. 3d 256, 270 n.4 (D.D.C. 2020) (rejecting the argument that FDA's analysis of scientific literature in an adjudication applied to future cases such that it was a legislative rule, and noting that, unlike in *Safari Club*, the agency's analysis was "in the context of adjudicating a particular set of disputed facts").

Likewise, Plaintiffs' reliance on cases involving IRS "listing decisions" misses the mark. Mot. 19 (citing *Green Rock LLC v. IRS*, 104 F.4th 220 (11th Cir. 2024); *Mann Constr., Inc. v. United States*, 27 F.4th 1138 (6th Cir. 2022)). Unlike FDA's highly fact-bound decision here, the IRS "create[d] new substantive duties" for an entire class of transactions, divorced from the facts of any particular transaction. *Mann*, 27 F.4th at 1144. Further, the IRS did not even contend its decisions were adjudications; the only issue was whether the listings were interpretive rules (which do not require notice and comment) or legislative rules. The other decisions Plaintiffs cite similarly fail to address the distinctions between rulemaking and adjudication. *See* Mot. 19.

B. Plaintiffs fail to explain how meaningful notice-and-comment rulemaking would have been possible here. Plaintiffs do not dispute that FDA's shortage determination centers on a core set of confidential facts that the agency cannot disclose, to a degree that it would be unlikely to

provide the public with a "meaningful" opportunity to comment if FDA were to publish a proposed rule based on a mostly, or entirely, confidential record. *Solite Corp. v. EPA*, 952 F.2d 473, 484 (D.C. Cir. 1991). Nor do they contest that the statute expressly permits FDA to *withhold* the very *existence* of a shortage if disclosure would adversely affect the public health. *See* 21 U.S.C. § 356e(c)(3). Plaintiffs merely point to resources for agency best practices when rulemaking involves some confidential information. Mot. 22. But it is not reasonable to conclude that the same statute requiring FDA to maintain an up-to-date list of drugs in shortage while keeping confidential the factual material most critical to that listing determination *also* requires public notice-and-comment procedures.

3. Any procedural error was harmless

Even if FDA's determination that the shortage was resolved should have been subject to notice and comment, any error would be harmless. *See* 5 U.S.C. § 706. If an agency errs by not following notice-and-comment procedures, the error is harmless if "the lack of notice and comment did not prejudice" plaintiffs. *City of Arlington*, 668 F.3d at 244. That is the case here.

FDA's website states that "Patients, healthcare providers, organizations, and other interested parties may submit information to FDA regarding the status of an existing shortage by emailing drugshortages@fda.hhs.gov." FDA App. 50. Plaintiffs and others did in fact send FDA comments regarding the semaglutide shortage through this route. *See, e.g.*, FDA App. 44–49. FDA also maintains an open docket soliciting information regarding compounding where any individual may provide information on the compounding of human drug products, including the compounding of drugs on the shortage list. *See* https://www.regulations.gov/docket/FDA-2015-N-0030. As of the date of FDA's decision, that docket had thousands of comments, including comments relating to the semaglutide shortage which FDA addressed in its decision. App. 51. Though FDA was unable to disclose the most critical factual material to commenters, FDA "received and considered comments from" a variety of "interested parties," *City of Arlington*, 668 F.3d at 245, including from individual patients, pharmacy compounders, outsourcing

facilities, trade associations, and telehealth companies, *see* App. 71. Because Plaintiffs "received notice of the issues pending before [FDA] and had the ability to comment on [them] in the agency proceedings," and FDA already "considered and addressed" the issues raised in this litigation, Plaintiffs suffered no prejudice from a lack of notice and comment. *City of Arlington*, 668 F.3d at 245–46.

Plaintiffs speculate that publishing notice in the Federal Register *might* have led to additional public comments, Mot. 23–24, but they identify no one who claims to have missed out on the chance to comment. Plaintiffs also fault FDA for allegedly using a "new methodology" in its shortage determination, deride that method as "idiosyncratic," and claim that a notice of proposed rulemaking would have informed interested parties as to the "kinds of metrics the agency was relying on." *Id.* There was no mystery here. The statute required FDA to determine whether nationwide supply of Novo's product could satisfy current demand and projected demand, 21 U.S.C. § 356c(h)(2), so detailed nationwide supply-and-demand data are most useful, *e.g.*, App. 29–31. Conversely, anecdotal consumer reports and unscientific internet polls are inherently less reliable or probative. App. 46–52.[6] Plaintiffs had the opportunity to submit information, were not limited in doing so, and in fact submitted as many comments as they wished, making clear that the absence of notice-and-comment procedures did not prejudice them.

In sum, FDA properly proceeded by adjudication and declaratory order and any error was harmless. Plaintiffs are thus not likely to succeed on the merits of their procedural claim.

II. The Balance of Equities and Public Interest Strongly Weigh Against Injunctive Relief

Denying the proposed injunction serves the public interest because it maximizes patient safety and credits the balance Congress struck between incentivizing drug development and

[6] FDA publicly endorses the government-wide "[t]ips for submitting effective comments," including to "support your comment with substantive data, facts, and/or expert opinions." Regulations.gov, "Tips for Submitting Effective Comments," https://perma.cc/F9UD-96NB (last accessed Apr. 9, 2025); *see* FDA, "Guide to Submitting Comments to the FDA," https://www.fda.gov/patients/guide-submitting-comments-fda (last accessed Apr. 10, 2025) (directing visitors to that guide).

allowing compounding during temporary drug shortages. Neither Plaintiffs' profit motives nor general concerns about medication access outweigh these interests.

Indisputably, compounded drugs do not provide patients with the full complement of safety protections that accompany FDA-approved drugs. Compounded drugs "have not undergone FDA premarket review for safety, effectiveness, and quality, and lack a premarket inspection and finding of manufacturing quality that is part of the drug approval process." App. 58. Products from 503A pharmacies offer even fewer safety assurances to patients because they are not required to comply with cGMP regulations that help ensure the quality of pharmaceuticals, *id.*, nor are they subject to the statutory adverse event reporting requirements that apply to outsourcing facilities. Accordingly, it is in the interest of public health for the statutory restrictions on compounding to apply when an approved version of a medication is available.

In addition, an injunction would upset the balance Congress struck between incentivizing conventional drug manufacturers to develop innovative drugs and the public's need for supplemental supplies of those drugs during shortages. Congress determined that certain drug products like those at issue here are generally protected by statutory exclusivity for five years. 21 U.S.C. § 355(c)(3)(E)(ii). Unnecessarily prolonging the period in which compounders may produce certain copies of such an FDA-approved drug diminishes these statutory rights and, in turn, diminishes incentives for drug development and manufacturing, harming the public's interest in future innovations.

To be sure, as Plaintiffs contend, the public has an interest in access to medical treatments, *see* Mot. 25, but in so arguing they create a false equivalency between compounded drugs and approved drugs. Congress determined where the public interest lies in the very balance it struck between incentives for drug development and public access to compounded drugs during a period of shortage. Moreover, in light of Novo's manufacturing capacity and existing stock of semaglutide, the public will not be deprived of access to semaglutide absent injunctive relief. To the extent that the access concerns Plaintiffs invoke are functions of the approved drug's cost and limitations on insurance coverage, their issue is with other aspects of the healthcare system, not

the instant factual question whether the semaglutide shortage was resolved, and thus fell outside FDA's statutory authority to address.

Nor is the public interest outweighed by any financial loss to Plaintiffs. The financial opportunity for compounders presented by the semaglutide shortage was always temporary, and FDA has afforded Plaintiffs substantial enforcement discretion to facilitate the orderly wind-down of their semaglutide manufacturing. The public interest and balance of equities weigh heavily against an injunction.

CONCLUSION

Plaintiffs' motion for a preliminary injunction should be denied.

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CERTIFICATE OF SERVICE

I hereby certify that this document, filed through the CM/ECF system, will be sent by electronic mail to the registered participants as identified on the Notice of Electronic Filing.

April 10, 2025

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